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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/542,935	04/04/2000	Maria Palasis	02844/56301	5876

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EXAMINER	
WHITEMAN, BRIAN A	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 02/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/542,935	PALASIS, MARIA	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 12/4/03.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1,3,10-12,17-20,23-27,34-38,42-44,47,49-52,54-56,58,59 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1,3,10-12,17-20,23-27,34-38,42-44,47,49-52,54-56,58,59 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Final Rejection

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/30/03 has been entered.

Claims 1, 3, 10-12, 17-20, 23-27, 34-38, 42-44, 47, 49-52, 54-56, 58, and 59 are pending examination.

Applicant's traversal, the amendment to claims 1, 17, 26 and 37, the cancellation of claims 2, 4-8, 13-16, 21, 22, 28, 29, 31, 40, 41, 45, 46, and 48 in paper filed on 12/3/03 is acknowledged and considered.

Priority

The insertion "This Application is a CIP of US 09/204,254 filed on 12/3/98 now US Patent 6,369,039" on the first line of the specification is acknowledged.

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: the claims remain unsupported under 35 U.S.C. 112, first paragraph, as failing to comply with the 112 first paragraph written description as set forth in the 112 first paragraph written description rejection in the previous office action mailed on 6/4/03.

Applicant's arguments filed 12/3/03 have been fully considered but they are not persuasive for the same reasons as set forth under the response to the applicant's argument against the 112 first paragraph written description rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 10-12, 17-20, 23-27, 34-38, 42-44, 47, 49-52, 54-56, 58, and 59 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Amended claims 1 and 26 filed on 3/17/03 introduced new subject matter into the application.

The original specification did not disclose making and using a medical device comprising a biocompatible structure carrying a genetic material, said biocompatible structure comprising a polymeric coating that coats at least a portion of said structure, said genetic material comprising: a) a first therapeutic agent comprising a vector containing a first polynucleotide encoding an angiogenic agent and b) a second therapeutic agent comprising a non-genetic therapeutic agent, wherein said non-genetic therapeutic agent is an angiogenic agent.

In addition, the specification set forth a list of products that the vector and the carrier can carry (pages 16-19). However, nothing in the specification would lead one to the particular combination set forth in the amended claims. "It is not sufficient for purposes of the written description requirement of Section 112 that the disclosure, when combined with the knowledge in the art, would lead one to speculate as to modifications that the inventor might have envisioned, but failed to disclose." *Lockwood v. American Airlines Inc.*, 41 USPQ2d 1961, 1966 (CAFC 1997).

Applicant's arguments filed 12/3/03 have been fully considered but they are not persuasive.

With respect to Applicant's assertion that in view of MPEP 2131.05 II (see Fujikawa v. Wattanasin, 93 F.3d 1559, 1571 39 USPQ2d 1895 (Fed. Cir. 1996), the clear description in the subject specification goes well beyond one that would merely "reasonably lead' the skilled artisan to the claimed invention, as was found lacking in *Fujikawa, supra* (see pages 8-9). The assertion is not found persuasive for the reasons of record (see advisory action mailed on 10/29/03) and because in view of MPEP 2131.05 II and *Lockwood v. American Airlines Inc.*, 41 USPQ2d 1961, 1966 (CAFC 1997), the assertion is not supported by any evidence of record. Also see MPEP § 716.01(c). There is nothing in the as-filed application that would reasonably lead one skilled to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 50, 52, and 56 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "small molecule" in claim 50 is a relative term, which renders the claim indefinite. The term "small molecule" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The disclosure does not define the metes and bounds of the term. One skilled in the art understands that there are molecules that are considered a small molecule (e.g. DNA, RNA, organic compound, peptide, inorganic compounds, etc.) and the disclosure does not claim or particularly point out what is a small molecule.

Applicant's arguments filed 12/3/03 have been fully considered but they are not persuasive for the reasons of record (see advisory action mailed on 10/29/03). More specifically, as mentioned before the specification does not provide a definition for the term. Furthermore, the assertion that one skilled in the art would understand the term to be defined as a molecule of <600-700 molecular weight (See. Synthesis and Application of Small Molecules Libraries, Chem. Rev. 196, 96 555-6000), is not found persuasive because the article cited for support of the definition is not properly incorporated into the specification (See MPEP 608.01(p)). Furthermore, applicant states, "Applicant does not disagree that the term may encompass the molecules listed by the examiner-if those molecules have a weight as defined by one of skill in

the art (see page 11)." Other than the assertion, the applicant provides no evidence to support the assertion. See MPEP § 716.01(c).

In addition, with respect to applicant's argument that the applicant has not used the term in way which gives a meaning repugnant to the usual meaning of the term (See, *In Re Hill*, 161PQ482 (CCPA 1947), the argument is not found persuasive because the usual meaning of the term is not defined by the specification. See also MPEP § 716.01(c).

Furthermore, MPEP 2173.05(a) recites:

> If the claims, read in light of the specification, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the statute (35 U.S.C. 112, second paragraph) demands no more. Shatterproof Glass Corp. v. Libbey Owens Ford Co.,758 F.2d 613, 225 USPQ 634 (Fed. Cir. 1985) (interpretation of "freely supporting" in method claims directed to treatment of a glass sheet); Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 USPQ 81 (Fed. Cir. 1986) (interpretation of a limitation specifying a numerical value for antibody affinity where the method of calculation was known in the art at the time of filing to be imprecise). This does not mean that the examiner must accept the best effort of applicant. If the proposed language is not considered as precise as the subject matter permits, the examiner should provide reasons to support the conclusion of indefiniteness.

The specification has not provided a definition of the term and the language is not considered precise for the reasons set forth above, the term makes the claim indefinite.

The term "vector is site specific" in claims 52 and 56 is a relative term, which render the claims indefinite. The term "site specific" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The disclosure does not define the metes and bounds of the term. One skilled in the art understands that vectors can be modified to selectively replicate or selectively target a site in a mammal and the disclosure does not claim or particularly point out which definition of the term is being used.

Applicant's arguments filed 12/3/03 have been fully considered but they are not persuasive.

Applicant states, "the examiner indicates an erroneous understanding of site specificity as relating to selective replication or targeting within a mammal."

Applicant argues, "the description provided is used according to the well known definition of the term (See, *In Re Hill*)" and "It has been shown that AAV vectors mutant for the rep gene, lack the ability to integrate site-specifically. See: Satoh et al. J. Virol. 2000 November; 74, 10631-10638)." See pages 11-12.

The argument is not found persuasive for the reasons of record and because as noted by applicant the components of the vector (e.g., ITR and Rep78/68 protein) are responsible for the vector being site specific and not the vector itself.

Response to Arguments

Applicant's arguments, filed 12/3/03, with respect to 112 second paragraph rejections have been fully considered and are persuasive. The rejection of claims 17, 30, 37 has been

withdrawn because of the amendment to claims 17, 30, 37 and the cancellation of claim 30. See pages 10-12 of applicants' traversal.

Applicant's arguments, filed 12/3/03, with respect to 102(b) rejection over Isner have been fully considered and are persuasive. The rejection of claims 1, 10, 11, 12, 19, 24, 26, 30, 34, 35, 37, 44, 49, 50, 52, 54, 55, 56, 58, and 59 has been withdrawn because of the amendment to independent claims 1 and 26 with the negative limitation "wherein the second therapeutic agent does not include nitric oxide synthase" and the cancellation of claim 30. See pages 12-14 of applicants' traversal.

Applicant's arguments, filed 12/3/03, with respect to 103 rejection over Isner in further view of Donovan have been fully considered and are persuasive. The rejection of claims 1, 17, 19, 20, 26, 42, 44, and 47 has been withdrawn because of the amendment to independent claims 1 and 26 with the negative limitation "wherein the second therapeutic agent does not include nitric oxide synthase". See pages 14-15 of applicants' traversal.

Applicant's arguments, filed 12/3/03, with respect to 103 rejection over Isner in further view of Branellec have been fully considered and are persuasive. The rejection of claims 1, 3, 24, 25, 26, and 27 has been withdrawn because of the amendment to independent claims 1 and 26 with the negative limitation "wherein the second therapeutic agent does not include nitric oxide synthase". See page 15 of applicants' traversal.

Applicant's arguments, filed 12/3/03, with respect to 103 rejection over Isner in further view of Lennox have been fully considered and are persuasive. The rejection of claims 1, 18, 25, and 26 has been withdrawn because of the amendment to independent claims 1 and 26 with the

negative limitation "wherein the second therapeutic agent does not include nitric oxide synthase". See pages 15-16 of applicants' traversal.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764.

The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, SPE - Art Unit 1635, can be reached at (571) 272-0760.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman
Patent Examiner, Group 1635

Scott D. Priebe

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER